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eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century

Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS
eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century

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eHealth Action Plan 2012-2020 – innovative healthcare for the 21st century

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EXECUTIVE SUMMARY

The eHealth Action Plan 2012- 2020 responds to the requests of the EPSCO Council in its December 2009 Conclusions on Safe and efficient healthcare through eHealth. Notably, the Council called upon the Commission for support "to bring forward eHealth deployment and actual use of Interoperable eHealth services within and between national healthcare systems" and to "update the eHealth Action Plan".

Building on these requests, the operational goal of the Action Plan is to break down persistent barriers and realise the vision of the Europe 2020 Strategy in the area of eHealth. It aims to improve the quality of life of European citizens; provide equal access to high quality and sustainable health care systems to all European citizens; and enhance the competitiveness of EU industry in the area of eHealth.

Since the adoption of the first eHealth Action Plan in 2004, significant progress has been made. Notably, political awareness around eHealth has risen significantly. This has led to many EU Member States, regions and healthcare providers committing to: widespread deployment of eHealth solutions, enhancing legal certainty and improving technical guidance. While all the planned actions defined in the 2004 eHealth Action Plan have been undertaken and progress has been made, challenges and barriers still remain. Many of the challenges are related to demographic change, an increase in the incidence of chronic diseases, the growing demand for high quality services and the impossibility to increase the number of resources accordingly. Increased mobility of citizens (patients and health professionals) within the EU and a shortage of professionals also threaten the future health systems as well as the principle of equity. In the face of all of these challenges, eHealth can play a beneficial role. Today the range of possible Information and Communication Technology (ICT) applications in the health sector is enormous. The technology has progressed significantly and many estimate that ICT implementation can result in care that is higher in quality, safer and more responsive to patients' needs and, at the same time, more efficient (appropriate, available, and less wasteful). eHealth advocates point to the potential reduction in medication errors as a critical advantage of the information system and electronic health record (EHR), but also the improvement of accessibility as a strategic instrument to decrease inequalities.

The eHealth Action Plan 2012 - 2020 was developed following a public consultation drawing on expertise across the eHealth stakeholder community, the recommendations of the eHealth Task Force and the review of evidence. The new Action Plan has been designed following a methodology of evidence-informed policy development which confirmed that the main barriers to deploying eHealth solutions are lack of users' awareness of the benefits, a lack of ehealth literacy, a lack of evidence of cost-effectiveness and interoperability. It should be noted that eHealth penetration, digital literacy and ICT use vary widely across EU Member States. Socio-political and economic differences as well as variations in health systems, health outcomes and health workforces also exist. As such, the cooperation and partnership of all Members State and all stakeholders should be essential to achieve the goals of the Action Plan.

The main body of evidence for the effectiveness of eHealth services is currently concentrated in three areas: health promotion and prevention, chronic diseases and mental health intervention. While there is evidence of the effectiveness of telemedicine, cost-benefit

analysis is often lacking. Going forward, such evaluation will play an important role in ensuring the success and the sustainability of future health systems.

The findings discussed in this staff working document point to a number of practices or approaches that could be employed for improving and accelerating the adoption and use of health ICTs. As these typically imply trade-offs with competing goals, policy makers must determine whether the expected benefits from these practices are likely to outweigh the costs of implementation in a particular situation. This document highlights an absence of robust monitoring and evaluation of programmes and projects. Measuring the impacts of ICTs is difficult for a number of reasons, but would be crucial to demonstrate the real added value of eHealth solutions. Consequently, the new eHealth Action Plan is addressing evidence-based implementation of eHealth solutions, promoting evaluation and research including the Health Technology Assessment (HTA) approach in order to define the essential elements to ensure a successful and efficient deployment of eHealth.

ICT implementation may have effects that are multidimensional and often may be uncertain in their reach and scope and difficult to control. In addition, the realisation of benefits from ICT implementation strongly depends on contextual conditions[1]. For example, moving to an EHR in its fullest form is not just a technical innovation; it is a cultural transformation. Changes in management are vital for successful uptake, and failure to build in processes for effecting the necessary organisational transformations will reduce both uptake and impact. Participation and involvement of Member State in this process is essential.

The adoption in 2011 of the Directive on the Application of Patients' Rights in Cross Border Healthcare[2] and its Article 14 establishing the eHealth Network, marks a further step towards formal cooperation on eHealth. All Member States are now participating in the eHealth Network, with the aim to maximise social and economic benefits through eHealth systems and interoperability (one of the most important barriers).

The actions focus on European added value by means of pan-European policy and legislative actions, transformative research and innovation, and interoperability and deployment in order to facilitate a common eHealth and wellbeing innovation space, in which citizens' rights are protected, their mobility across the European Union is facilitated and equity and social cohesion for all is promoted.

Considering all of the above, the Commission will work to achieve following operational objectives:

– achieving wider interoperability of eHealth services;

– supporting research, development and innovation in eHealth and wellbeing to address the availability of user-friendly tools and services;

– facilitating uptake and ensuring wider deployment;

– promoting international cooperation.

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1 Improving Health Sector Efficiency: The Role of Information and Communication Technologies. OECD 2010. http://www.oecd.org/document/61/0,3746,en_2649_33929_45501565_1_1_1_1,00.html

2 The Network was established under Article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF , OJ L 88, 4.4.2011,p.45.

1. INTRODUCTION

The 2004 eHealth Action Plan[3] set out the first steps necessary for widespread adoption of eHealth technologies across the EU.

In December 2009 within the framework of the EPSCO Council, Member States adopted ***Council Conclusions on Safe and efficient healthcare through eHealth***[4]. In these Conclusions, the Council recognises the contribution that eHealth can bring to healthcare systems, it underlines the common challenges all healthcare systems are facing and called upon the Commission for support "to bring forward eHealth deployment and actual use of Interoperable eHealth services within and between national healthcare systems". Finally, the Council specifically called on the Commission to "update the eHealth Action Plan".

To respond to this call, to reflect the progress made so far in eHealth and provide support to Member States and stakeholders to make further progress, the Commission is updating the eHealth Action Plan. The new Action Plan will also be an opportunity to consolidate the actions which have been undertaken or planned so far in a number of initiatives, while providing for a global strategic vision on eHealth. This Action Plan also aims at stimulating a policy debate on how innovation can contribute to rethinking the way in which healthcare is provided today, by considering the latest developments in technology, innovative services and the growing impact of new media on the health and wellbeing systems.

In this document:

– eHealth means ICT tools and services for health. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals. Examples include health information networks, electronic health records, telemedicine services, wearable and portable systems which communicate, health portals, and many other ICT-based tools assisting disease prevention, diagnosis, treatment and follow up.

– ICT for wellbeing is the use of ICT in products, services and processes, in order to directly or indirectly improve the quality of life and wellbeing status of EU citizens. Wellbeing is a person's experience of positive and negative emotions, satisfaction, vitality, resilience, self-esteem and sense of purpose and meaning. Social well-being has two main components: supportive relationships and a feeling of trust and belonging; together they form a picture of what everyone really wants: a fulfilling and happy life[5] . It is increasingly recognized that the major factors of ill-health and the major assets for health are best addressed by engaging non-health sectors and citizens[6].

– Telemedicine is the provision of healthcare services, through use of ICT, in situations where the health professional and the patient (or two health professionals)

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3 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF

4 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:302:0012:0014:EN:PDF

5 New Economics Foundation (2011).Measuring our progress: the power of well-being. London, New Economics Foundation (http://www.wikiprogress.org/images//Measuring_our_progress webReady.pdf, accessed 30 May 2012)

6 Governance for Health and Wellbeing in the 21st century. http://www.euro.who.int/__data/assets/pdf_file/0019/171334/RC62BD01-Governance-for-Health-Web.pdf

are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients.

2. THE CONTEXT OF THE INITIATIVE

The Europe 2020 Strategy emphasises that knowledge and innovation are key to help Europe exit the current socio-economic crisis[7]. In this context, it highlights the potential of Europe's digital economy to help Europe achieve smart, sustainable and inclusive growth.

The Digital Agenda for Europe ('DAE')[8], one of the flagship initiatives of the Europe 2020 Strategy aims to deliver sustainable economic and social benefits from a digital single market. The sustainability of healthcare systems is identified as a priority area which can greatly benefit from the use of information and communication technologies (ICT) by enabling patient empowerment and continuity of care.

Innovation Union, also a Europe 2020 flagship, aims to improve conditions and access to finance for research and innovation in Europe, to ensure that innovative ideas can be turned into products and services that create growth and jobs. Launched under Innovation Union, the pilot European Innovation Partnership on Active and Healthy Ageing[9], aims at increasing the average healthy lifespan in the EU by two years by 2020. This will be achieved inter alia by scaling up uptake of innovative eHealth tools and services which would lead to empowering citizens, in particular older people, increasing sustainability of healthcare systems and generating growth.

The new eHealth Action Plan 2012 - 2020 builds on the 2004 eHealth Action Plan which marked the beginning of closer cooperation between EU Member States in the area of eHealth. This led, in 2008, to more formal cooperation through the Large Scale Pilot epSOS[10] and eGovernance Initiative. The establishment of the eHealth Network, set up under Article 14 of the Directive on the Application of Patients' Rights in Cross Border Healthcare[11] marks a further step towards formal cooperation on eHealth.[12] The eHealth Network will be giving advice and endorsing guidelines. The Connecting Europe Facility (CEF)[13] has been set up to facilitate the deployment of cross-border interoperable ICT services of general interest, also eHealth. This new instrument, taking over the expert work done by the eHealth Governance Initiative, will organise expert groups for cross border deployment, including at the organisational level. (See the governance chart in the annex).

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7 *EU2020 strategy, op.cit.* p. 3.

8 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0245:FIN:EN:PDF

9 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0083:FIN:EN:PDF

10 The epSOS pilot commits 23 National Health Ministries to work together for the deployment of interoperable patient summaries and ePrescription solutions throughout Europe.

11 The Network was established under Article 14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF , OJ L 88, 4.4.2011,p.45.

12 The Network "*aims at delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare*".

13 http://ec.europa.eu/commission_2010-2014/president/news/speeches-statements/pdf/20111019_2_en.pdf

3. THE 2004 EHEALTH ACTION PLAN

The first eHealth Action Plan defined the following main challenges:

- *Leadership from healthcare authorities and providers,* in particular focusing on financial and organisational aspects, which are considered essential elements for the successful deployment of eHealth.

- *Market fragmentation, lack of interoperability, ineffective standardisation:* The main reasons for market fragmentation are related to lack of regulation and standards at EU level, while healthcare systems remain highly regulated through various national regulations.

- Legal uncertainty in deploying eHealth (cross border) services, ineffective funding, reimbursement, procurement and sustainable business models

- *Limited awareness of benefits among authorities and health professionals:* the Action Plan identified the need for a European-wide public health portal that would be a flexible information technology platform to disseminate evidence-based information on public health relevant to European citizens, while providing a single point of access to information on health.

- *Specific concerns on privacy and protection of personal data, leading to lack of confidence and wide acceptance*: building trust is a prerequisite to the development of an information society as well as eHealth services.

- *Insufficient infrastructure* (for example the lack of broadband in remote areas, essential for telemedicine services): a top priority for health providers using an eHealth system is the speed in getting the desired, high-quality results. Online health services can only work thanks to high speed broadband connections, which depend on appropriate infrastructures.

3.1. An evaluation of the 2004 eHealth Action Plan

Since its launch, the eHealth Action Plan has contributed to bringing forward specific priority areas which have then been embedded in other policy initiatives and projects. The most relevant ones are presented below following the structure of the objectives of the 2004 eHealth Action Plan:

Increased political awareness:

- Council Conclusions on safe and efficient healthcare through eHealth 2009;
- Ministerial/conference Declarations[14];
- DAE key actions 13 and 14;
- European Innovation Partnership on "Active and Healthy Ageing";
- Article 14 of the recently adopted Directive on the application of patients' rights in cross-border healthcare[15] as regards mutual assistance and cooperation

[14] Member States have strengthened their cooperation in the field of eHealth through Ministerial Declarations following the annual eHealth Conferences (2003- 2010) and a set of high level meetings between State Secretaries (and/or equivalent level) to define European eHealth Governance. This shows that eHealth has risen in the health policy agenda and has developed growing political importance.

[15] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/119514.pdf

among Member States, including on the local and regional level, for providing cross-border healthcare services;

Technical guidance

– European Commission Recommendation on cross-border interoperability of electronic health records systems

Improving legal certainty

– Staff Working Paper on the Applicability of the existing EU legal framework to telemedicine services – a follow-up action of the 2008 Communication on Telemedicine16. This Staff Working Document analyses the EU legal framework applicable to telemedicine services and aims to enhance legal clarity in the sector ;
– Directive on the application of patients' rights in cross-border healthcare.

Commitment to large-scale deployment of eHealth solutions:

– epSOS project[17] – defining services for a pan-European electronic patient summary and ePrescription by creating building blocks for the future unification of the European Information Space and considerably increasing the innovation potential of European enterprises.

Significant progress has been achieved in the area of increasing political awareness, committing to widespread deployment of eHealth solutions, enhancing legal certainty and improving technical guidance.

While progress has been made, the Report "Assessing the progress of the eHealth Action Plan for the period 2004 – 2010"[18] describes in addition to the achievements the remaining challenges. These include those actions which are the most significant in their implications and in their scale (and are indeed those which could be considered closest to a shift towards a European eHealth area):

– identification of a common approach among the Member States for patient identifiers;

– identification of interoperability standards for electronic health records (EHRs) among the Member States;

– adoption of common schemes for conformity testing and accreditation;

– creation of a framework for greater legal certainty of eHealth products and services;

– provision of online services in telemedicine and ePrescription by the majority of European health organisations and regions.

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16 Communication of the Commission on telemedicine for the benefit of patients, healthcare systems and society, COM(2008)689,

http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF

17 http://www.epsos.eu/

18 http://ec.europa.eu/information_society/activities/health/docs/policy/ehap_assess082011.pdf

4. PROBLEM DEFINITION

4.1. Sustainability of healthcare and social systems

The healthcare delivery systems in Member States are increasingly faced with the challenges related to the growing demand for high quality services and the impossibility to increase the number of resources accordingly.

An ageing population, a higher incidence of chronic diseases and a shortage of financial and human resources devoted to healthcare are among the key factors leading to this very challenging situation both for health and social care systems. If current trends of fertility and mortality continue there will be important changes in the age structure of the population with a huge impact on the macroeconomic situation in Europe. Eurostat projects that by 2060 the EU population will be both smaller and older than in 2008. Most countries will see a drop in both young (0-14) and working age populations (15-64). The number of people aged 60 and above in the EU is now raising by more than two million every year, roughly twice the rate observed until about three years ago. The working age contingent, the main contributor to social protection systems is expected to fall dramatically from 67% to 56% of the total population. While the younger population shrinks, the share of the elderly (65+) and very old (80+) population in the EU is projected to grow by an average of 13% and 8% respectively.

Public expenditure on healthcare is expected to grow by 1½ percentage points of GDP in the EU by 2060. Institutional and policy changes as well as demographic trends are expected to transform our societies considerably, undermining intergenerational solidarity and creating new demands on future generations.

Healthcare is a constantly growing component of public finances. The share of total government spending on healthcare has grown since the 1990s with the increases exceeding inflation rates. Healthcare accounts for 9 % of GDP but represents between 12% and 15% of government spending in most EU countries. The ongoing economic uncertainty brings into sharp focus the fact that current healthcare models are financially unsustainable. eHealth with its promise of more efficient and cost effective care is critical to the survival of the system of healthcare in Europe.

On the other hand economists consider health as a component of human capital or add it to economic models as a variable termed “health capital”[19]. Being in good health has long been shown to impact positively on investment into continuing education, reduce the natural human capital depreciation rate and the number of work days lost. In addition, it delays retirement and decreases hospital days – both of these contribute to systemic socio-economic sustainability.

Without better tailored and more effective health and social care services, Europe's social and health models will be seriously jeopradised. For example, a recent report on health systems[20] emphasises the need to increase effectiveness and efficiency in healthcare. Reduction of unnecessary use of specialists and hospital care while improving primary healthcare services and better use of personalised health systems can help deliver better and more efficient care.

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19 See sources from the economic literature discussed in Codagnone (2009a: p. 27)

20 Joint Report on Health Systems, the European Commission and the Economic Policy Committee(AWG), 2010, http://ec.europa.eu/economy_finance/publications/occasional_paper/2010/op74_en.htm

A study ' European countries on their journey towards national eHealth infrastructures'[21] stated that when looking at financing sources for development and investment in eHealth infrastructures and applications, a mixed picture emerges. Across Europe, the primary sources of funding are government or quasi-public sources, e.g. the general budget for health, as well as dedicated ICT budgets or special levies on statutory health insurances. Considering that individual service providers usually do not have an incentive to establish eHealth infrastructures for all, this result is not surprising. To compensate for market failure and allow a network effect to kick in, adopting a 'public good' perspective of eHealth infrastructure seems warranted. Recurring public budgets dedicated specifically to "the reimbursement of eHealth services" are still the exception, whereas there is widespread use of project-based sourcing. Sometimes private and public insurance companies or public technology or innovation agencies are involved in temporary financing.

4.2. Ageing population and growing incidence and prevalence of chronic diseases

As life expectancy increases, so does the prevalence of chronic disease. Currently chronic disease is a global epidemic which accounts for more than 60% of deaths[22] and disability. The WHO recognised[23] the rapidly growing magnitude of non communicable diseases that affects people of all ages, gender, race and income levels, and further poor populations and those living in vulnerable situations. The burden of chronic disease for the health and social system and for the economy and work force is enormous. Improving control and prevention of chronic conditions is a global challenge.

In fact, WHO is urging Member States to draw upon, based on national contexts, the policies, strategies, programmes and interventions, and tools on the prevention and control of Non-communicable Diseases, in order to promote, establish or support and strengthen, as appropriate, multisectoral national policies and plans.

Patient empowerment is essential to support better control of chronic conditions. Against this backdrop there is clearly a need for improved quality and more accessible information online, increasing awareness and promotion of healthy lifestyles[24] among citizens. In this context, innovative systems supporting patients to better manage their conditions like, remote monitoring devices, can also contribute to patient empowerment, leading to better managment and increased quality of life[25].

4.3. Mobility of patients and health professionals and shortage of professionals

Due to growing levels of mobility of patients and professionals, demand for cross-border services is rising. Patients need secure and standard access to these services in cross-borders situations.

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21 http://www.ehealth-strategies.eu/report/eHealth_Strategies_Final_Report_Web.pdf

22 Monitoring Financial Flows for Health Research 2006: The changing landscape of health research for development. 71. 2006. Global Forum for Health Research

23 http://apps.who.int/iris/bitstream/10665/23846/1/B130_R7-en.pdf

24 Whether provided through web 2.0 or more traditional public and private information portals.

25 See JRC IPTS Strategic Intelligence Monitor on Personal Health Systems Phase 2 Report on best practices and key drivers of success at http://is.jrc.ec.europa.eu/pages/TFS/SIMPHS2.html

The mobility of patients[26] and health professionals within the EU is increasing.[27] On the other hand, new threats put at risk the future health system and its principle of equity. The number of practising physicians, general practitioners and practising nurses and midwives per 100,000 inhabitants has increased in the EU taken as a whole since the 1970s[25]. At the same time, the health workforce is ageing. On average in the EU, more than 60% of physicians are more than 45 years old, a proportion that has increased over time: from 44.4% in 1995 to more than 60% in 2008. In some countries, staff migration to countries in need of staff and offering higher wages can become a problem for the country of origin. A lack of and inadequately trained and practising staff combined with migration are undermining the capacity of Member States to ensure cost-effective delivery and equitable access to health care services.

eHealth can play a role in addressing the current challenges of the health system, providing healthcare to remote areas while decreasing the inequalities and variability of clinical practice in the Member States. The 2010 EU Citizenship Report underlined the role of eHealth in facilitating cross border healthcare[28].

4.4. Increased demand for high quality of care and investing in expensive technologies

In 2006 the Council of the European Union agreed to a set of Common Values and Principles in EU Health Systems. It invited the European Commission to ensure that these values and principles are respected when drafting specific proposals concerning health services. The overarching values considered are: Universality, Access to good quality care, Equity, Solidarity. The operating principles are: quality, safety, evidence based and ethical care, patient involvement, redress when things go wrong, privacy and confidentiality. However, health inequalities persist across the EU.

The quality of the healthcare system is often associated with the use of sophisticated technologies and advanced, costly medicines. A rising demand for services in a situation with limited resources that is worsened by the recent economic crisis, makes cost-effectiveness one of the most important goals in this area[29]**.** Investing in quality and containing cost while providing safety and equity care is a mandatory goal for health systems. The use of interoperable EHRs has been identified as a major opportunity for more efficient and better quality healthcare. Other technologies to support administrative or clinical processes provide a theoretical framework to ensure the quality and safety of the system. The need to improve the general governance (decision-making and management) of the health system has been tested by the Joint Report on Health Systems previously mentioned.

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26 Patient mobility is addressed specifically in a Communication from the Commission, COM(2004), entitled *Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union.*

27 Regulation 1408/71 that co-ordinates social security legal schemes has recently been amended to streamline and modernise access to health care across borders, particularly when undue delays occur in the patient's home Member State. In January 2004, the Commission adopted a proposal for a Directive on services in the internal market (COM(2004)2 final) which lays down a framework for the provision of services in the internal market, including health services, and for their reimbursement by the relevant health insurance institutions when healthcare is provided in another Member State.

28 EU Citizenship Report 2010 - Dismantling the obstacles to EU citizens' rights COM(2010) 603 final (pp. 8 and 9).

29 Joint Report on Health Systems, the European Commission and the Economic Policy Committee(AWG), 2010, http://ec.europa.eu/economy_finance/publications/occasional_paper/2010/op74_en.htm

4.5. Slow deployment of eHealth tools and services

Clinical and healthcare workflows, care models, and business processes are significantly more complex than equivalents in other sectors of the economy and less amenable to standardisation and streamlining by conventional eBusiness systems. Below, the results of the public consultation and the available evidence demonstrate other reasons and barriers for slow uptake of eHealth solutions including: the lack of awareness of, and confidence in, eHealth solutions among patients, citizens and healthcare professionals; lack of interoperability between eHealth solutions; limited large-scale evidence of the cost-effectiveness of eHealth tools and services; lack of legal clarity for health and wellbeing mobile applications and the lack of transparency regarding the utilisation of data collected by such applications; inadequate or fragmented legal frameworks including the lack of reimbursement schemes for eHealth services and the high start-up costs involved in setting up eHealth systems.

Successful EHRs and ePrescribing are not quick wins; they are sustainable wins. It takes at least four, and more typically, up to nine years. Average time to annual net benefit of the nine sites is seven years.[30]

5. CONSULTATION OF INTERESTED PARTIES

5.1. Stakeholder consultation

A public consultation on the eHAP ran from 31 March to 31 May 2011. It sought the views of interested parties on the proposed policy objectives to understand whether they were in line with their expectations while verifying whether there were additional areas requiring further action.

The draft questionnaire was discussed with Member States representatives within the framework of the i2010 subgroup on eHealth (Ad-hoc expert group on eHealth) during its meetings on 15 September 2010 and on 19 January 2011, when it was informally validated. It was also presented during the European Health Policy Forum on 21 October 2010 and to the eHealth Users – Stakeholders group, which included representatives of users of eHealth including professionals, patients and healthcare managers[31].

The consultation sought to validate four proposed objectives and to explore possible actions to be undertaken in the next years. The four objectives proposed were:

> Objective 1: Increase awareness of the benefits and opportunities of eHealth, and empower citizens, patients and healthcare professionals.
>
> Objective 2: Address issues currently impeding eHealth interoperability
>
> Objective 3: Improve legal certainty for eHealth
>
> Objective 4: Support research and innovation in eHealth and development of a competitive European market.

30 Economic Impact of Interoperable Electronic Health Records and ePrescription in Europe (01-2008/02-2009): http://ec.europa.eu/information_society/activities/health/docs/publications/201002ehrimpact_study-final.pdf

31 This group has been replaced by the eHealth Stakeholder group.

239 participants contributed to the consultation, representing a wide range of stakeholders including non-governmental organisations, academia, enterprises, health and social care providers and public authorities from many Member States.

The majority of respondents underlined four main actions to address barriers impeding the deployment of eHealth that the European Commission should take:

(1) Supporting systematic evaluation of the benefits and costs, effectiveness/usefulness of eHealth solutions;

(2) Improving interoperability and strengthening the evidence-based approach; and

(3) Facilitating cooperation between Member States and regions and,

(4) Exploring innovative financing and reimbursement schemes.

Most of participants (around 90-95%) agreed or partially agreed with the four main actions mentioned above.

Regarding specific actions for every objective, the majority of respondents believed that the main instrument to increase patients' awareness and trust on eHealth is an information campaign. Improving healthcare professionals' awareness and acceptance should be addressed through the inclusion of eHealth in medical curricula and training in the workplace; organising information campaigns and supporting the dissemination of good practices and results at professional conferences both at national and international level. Moreover, there is a strong need to provide evidence-based input and research and encourage the promotion of the benefits of eHealth by raising awareness as the evidence is being collected. According to 71% of respondents, the Commission should support the deployment of ICT systems for clinical use (decision support systems, EHR, ePrescription, Radiology Information Systems etc.).

The main action for the second objective, "address issues currently impeding eHealth interoperability", is taking steps to advance technical interoperability to facilitate de-fragmentation of the eHealth market. The most effective way of supporting European cooperation is to harmonise standards, profiles and technical specifications used to ensure cross border eHealth interoperability.

Regarding legal issues, most of the participants thought that encouraging professional associations, scientific societies and civil society representatives to promote the exchange of best practices through the development of guidelines and/or codes of conduct for eHealth services is an important area of action for the Commission. Data protection and liability should also be considered. The data protection reform foresees facilitating the adoption of codes of conduct to improve data protection in all sectors, including eHealth. The Commission encourages the drafting of such codes of conduct, to be approved by data protection authorities.

The objectives should be supported by providing funding for the scaling up of innovative eHealth solutions, for example by facilitating deployment of research results and providing more flexible financing mechanisms to support research and innovation. More emphasis should be put on international cooperation to promote benchmarking and evaluation projects in order to provide evidence to support deployment of eHealth solutions and to support new

innovative solutions such as Virtual Physiological Human, Personal Health Systems and ICT for Public Health.

The full Report on the results of the public consultation is published on the Commission's website[32].

5.2. Internal expertise

The Inter-service Steering Group on the eHealth Action Plan was established in December 2010 to support the drafting of the Communication. The following services were consulted: SG, LS, COMP, DIGIT, ECFIN, EMPL, ENTR, ENVI, JUST, JRC, MARKT, REGIO, RELEX, RTD, SANCO, TAXUD[33].

The group held three meetings: 8 February 2011, 14 April 2011 and 25 April 2012.

5.3. External expertise and input

Member States, within the framework of the i2010 subgroup on eHealth (Ad-hoc expert group on eHealth) at its meetings on 15 September 2010 and 19 January 2011, supported the public consultation questionnaire. The latter was also presented on 21 October 2010 to the eHealth Users – Stakeholders group during the European Health Policy Forum.

The eHealth Action Plan was discussed during the eHealth Week in Budapest in May 2011 and eHealth Week in Copenhagen in May 2012 at a meeting of the eHealth Stakeholder Group.

5.3.1. Task Force Report

As requested by Vice-President Kroes and Commissioner Dalli, a Task Force of thought leaders from politics, health and ICT was convened in May 2011. Its role was to examine the transformational role of technology in addressing the major challenges facing the health sector. The Task Force was chaired by the Estonian President, Mr Toomas Hendrik Ilves and met four times. Its final Report was presented on 7 May 2012 at eHealth week in Copenhagen.[34]

The Report highlights the critical preconditions for implementing eHealth effectively:

- Individuals are the owners and controllers of their own health data, with the right to make decisions over access to the data and to be informed about how it will be used. This principle is outlined in EU law and European jurisprudence but is rarely fully implemented in health systems.

- Large amounts of data currently sit in different silos within health and social care systems. If this data is released in an appropriate manner and used effectively it could transform the way that care is provided.

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32 http://ec.europa.eu/information_society/activities/health/docs/policy/ehap2012public-consult-report.pdf

33 Some DGs have changed since the launch of the ISSG

34 http://ec.europa.eu/information_society/activities/health/docs/policy/taskforce/redesigning_health-eu-for2020-ehtf-report2012.pdf

- The health sector has been slow to adopt new communication tools for a variety of institutional, economic and personal reasons. However, patients will increasingly demand that their health professionals and institutions use the same ubiquitous technology they use in everyday life.

- Full transparency on the performance of health professionals and institutions enables patients to make more informed choices about where and how they want to be treated. This will have real impact on resource allocation in health, as funding follows the patients.

- Service providers need to be aware that there may be sub-groups of the population that are outside the reach of eHealth tools - those without access to the internet/computers and individuals that choose not to interact intensively with technology.

The five recommendations presented in the Report are:

1. Create a legal framework and space to manage the explosion of health data. This needs to put in place the safeguards that will allow citizens to use health apps with confidence that their data is handled appropriately and subsequently it will create the conditions for the integration of user-generated data with official medical data so that care can be more integrated, personalised and useful for patients.

   – Create a 'beacon group' of Member States and regions committed to open data and eHealth. A leadership group from regions and countries that have invested in eHealth applications (such as Denmark, Sweden, Estonia, Spain) could be pioneers. The EU could facilitate such a group and finance experts who can evaluate eHealth projects from inception to delivery.

   – Support health literacy. As doctors are no longer the sole arbiters and interpreters of medical information for patients and as patients are playing a more active role, health data thus needs to be translatable into information that citizens understand.

   – New rules are needed to define how to integrate official data and user data to create a more holistic picture of situation of the patient in health care as well provide early feedback for preventive care. Certification of applications should be based on a set of principles for how health related data should be treated rather than regulation. Health institutions must publish the data on their performance and health outcomes.

   – Re-orient EU funding and policies - specific budget lines need to be agile, responsive and should foster the development of good ideas into fast prototyping and testing. Require transparency from institutions in health systems through procurement and funding criteria.

6. EVIDENCE INFORMED EHEALTH ACTION PLAN 2012 – 2020

In May 2005, the 58th World Health Assembly adopted a resolution acknowledging the Mexico Statement on Health Research, urging Member States "*to establish or strengthen*

mechanisms to transfer knowledge in support of evidence-based public health and health-care delivery systems, and evidence based health-related policies"[35].

The eHAP respects this resolution and, considering the hierarchy of evidence to decision making[36] (table 1), the impact assessment upon which it is based represents an additional scientific instrument to support and validate suggestions from experts and stakeholders who participated in the Public Consultation.

Table 1: Designations of levels of evidence [37]

Level of evidence	Study design
I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly-designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudorandomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test or pre-test/post-test

The objective of this section is to analyse the current scientific evidence supporting the objectives and actions of the new eHealth Acton Plan according to the evidence informed policy recommendation[38].

6.1. Methodology

Considering the revised hierarchy of the evidence and following recent recommendations, a systematic mini-review of systematic reviews, meta-analysis, health technology assessment (HTA) reports and other policy reports in response to specific research questions has been conducted.

Research questions

1. What are the main barriers and/or facilitators to deployment of eHealth solutions?

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35 World Health Assembly: Resolution on health research. 2005 http://www.who.int/rpc/meetings/58th_WHA_resolution.pdf World Health Organization

36 Merlin t, Weston A, Tooher. "Extending an evidence hierarchy to include topics other than treatment: revising the Australian "level of evidence" BMC Med Res Methodol. 2009 Jun 11;9:34

37 NHMRC. A guide to the development, implementation and evaluation of clinical practice guidelines. Canberra, ACT: National Health and Medical Research Council, Commonwealth of Australia; 1999

38 Lewin S, Bosch-Capblanch X, Oliver S, et al "Guidance for evidence-informed policies about Health system: Assessing how much confidence to place in the research evidence." PloS Med 2012; 9, 3:e1001187

2. What is the current status of eHealth in the EU and how to ensure successful and sustainable deployment of eHealth?

3. What is the evidence of the effectiveness and efficiency of eHealth and what research areas still need to gather large scale evidence to support wide deployment of telemedicine by 2020?

Literature Search

In order to respond to the questions above, a specific and restricted search in different sources was conducted.

In the context of the Methotelemed study[39], the European Commission funded an exhaustive systematic review of reviews on effectiveness of telemedicine. The literature search included extensive sources and databases up until January 2009. The results of this review which included 80 scientific papers were published in a peer reviewed journal[40].

After this date, the current literature search was conducted in Medline (Limit: meta-analysis) and Centre for Reviews and Dissemination (DARE and HTA) from 2009 to February 2012. The following terms were used for search: Telemedicine [MeSH Terms], eHealth, telecare, telehome, medical record system computerized [MeSH Terms].

Policy reports were selected from European studies published since 2004, papers from WHO, OECD, and another studies supporting benchmarking activities.

Papers included in this review were selected based on the following criteria: 1) Design: systematic review, meta-analysis, and evidence based policy recommendations; 2) Intervention and technology: any eHealth solution or service which describes a specific and reproducible intervention for any health field; 3) Participants: any stakeholder; 4) Outcomes: information about primary indicators/outcomes obtained with a reproducible, scientific and good quality methodology (minimising bias) is mandatory; 5) Answering at least one research question.

Exclusion criteria: systematic reviews/ meta-analysis from Medline without clear methodology in the abstract; interventions that are too complex or involving many different technologies making it impossible to extract individual outcomes.

Initial screening of identified articles was based on their abstracts. Articles from electronic data bases lacking an electronic abstract were initially excluded. The documents were classified according to research questions and objectives of the eHealth Action Plan. Data on the effectiveness of telemedicine were re-grouped by major topic.

[39] Methotelemed study Methodology to assess Telemedicine Applications (02-2009/02-2010) SMART 208/0064 http://ec.europa.eu/information_society/activities/health/studies/published/index_en.htm#Methodology_to_assess_Telemedicine_Applications

[40] Anne G. Ekelanda, Alison Bowesb, Signe Flottorpc "Effectiveness of telemedicine: A systematic review of Reviews". International journal of medical informatics 2010; 7 9 : 736–771

6.2. Results

From the 106 references regarding systematic reviews, meta-analysis and HTA reports, 57 documents were selected. Additionally to 20 policy documents or studies met the inclusion criteria. In total, 76 documents were analysed in order to respond to the research questions. All references can be found in the bibliography section.

From 76 documents, 53 focused on telemedicine or eHealth service, 5 on health information systems and EHR, and 18 were benchmarking studies or policy documents which reported on eHealth in general.

What are the main barriers and/or supporting factors to deploy eHealth solutions?

Six papers reported information about the barriers or facilitators to deploy eHealth solutions. The main barriers were the lack of awareness of, confidence in the benefit of eHealth; lack of user-friendly eHealth solutions; lack of interoperability between eHealth solutions; and limited large-scale evidence of the cost-effectiveness of potential improvements in healthcare processes.

McGinn et al[41] reported a systematic review on users' perceived barriers and facilitators to shared EHR implementation from 60 publications and they found that physicians, healthcare professionals and managers share many common supporting factors and barriers. Patients seem to have different views. While similarities can be found between groups, inter-group differences also show how the unique perspective of each user group needs to be taken into account. The results confirm that financial, time- related, and technical barriers are the most-cited barriers to EHR acceptance and adoption for patients, professionals and managers.

This point was also reported by a study on the benchmarking of acute hospitals[42]. According to medical directors, this situation might be due to prevailing interoperability problems. The medical directors identified interoperability between different departments' electronic patient record systems as the largest barrier to their implementation - 46% agreed that it was a barrier. This was followed by the lack of financial incentives for the staff to use these systems, a barrier that is more evident in large hospitals: 76% of medical directors in large hospitals agree that it is a barrier compared to only 46 % in the smallest hospitals. No clear barriers or impacts were identified concerning the adoption of telemonitoring. The low rate of implementation of telemonitoring might be explained by the medical directors' lack of perception that, in their hospitals, it will lead to improvements in quality of care if implemented. Seventy-eight per cent of medical directors state that telemonitoring would have little or no impact on the improvement of the quality of life of patients.

Moreover, patients were the only user group to identify supporting factors in a larger proportion than barriers and to consider autonomy (health empowerment and improved health self-management), as a positive EHR implementation factor. Patients highlight two factors, perceived usefulness and motivation to use EHRs, as main supporting factors for

[41] McGinn C et al. Comparision of user group's perspectives of barriers and facilitators to implementing electronic health records: a systematic review. BMC Medicine 2011, 9:46 http://www.biomedcentral.com/1741-7015/9/46

[42] Deloitte & Ipsos Belgium. "eHealth Benchmarking III" SMART 2009/0022. European Commission 2011. http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/ehealth_benchmarking_3_final_report.pdf

implementing EHR. Stakeholder groups identified[43] the following important characteristics of an Internet-based virtual clinic: being based on personal needs; having the facility to communicate; being quick and easy to use.

Other study[44]results indicated that consumers are ready to accept EHRs as long as they can be assured of the security of the system. Professionals' acceptance is a key factor in supporting deployment and usability of eHealth. Professionals play a relevant role in motivating patients to use ICT and to support self-management and autonomy. However, that is only possible if they believe eHealth is useful and effective. Another study published by the European Commission[45] showed that European general practitioners (GPs) are positive about the role of ICT in health care. They have a clear idea of what would facilitate a wider diffusion of eHealth use. However, while eHealth users do not perceive any major barriers, non-users are more critical. A lack of IT training for GPs is probably the strongest hindering factor. The former result is well in line with other data indicating that only a minority of GPs in Greece (38%), Latvia (29%), Poland (30%) and Romania (10%) receive IT support from professional service providers — compared to 74% on average across the 27 EU Member States as a whole.

Patients' attitudes about the use of Web messaging and online access to their EHR were mostly positive. At the same time, clinicians were less positive about using electronic communication than their patients[46]

Hardiker and Grant[47] in a systematic review of 50 articles looking for barriers and factors that affect engagement with eHealth services, recommended: targeted efforts to engage those underserved by eHealth; maximizing exposure to eHealth across all groups of society; improving access to computers and the internet; appropriate design and delivery; ensuring content is relevant to different audiences; capitalizing on the interest in Social Computing; and clarifying the role of health workers in the delivery of eHealth.

JRC-IPTS found within its analysis of Integrated Personal Health and Care Services in Europe, found that the frontrunners, in terms of eHealth and IPHS deployment (i.e.g. Denmark, England and, Scotland), show a combination of policy towards integrated care, incentives framework and funding mechanisms in place. Moreover, they offer official portals for public health services providing access to health information to citizens, patients and even health professionals. In this manner, they encourage empowerment[48].

What is the current status of eHealth in the EU and how to ensure successful and sustainable deployment of eHealth in the current socio-economic situation?

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43 Armstrong N et al Stakeholder perspectives on the development of a virtual clinic for diabetes care: qualitative study. J Med Internet Res. 2007 Aug 9;9(3):e23.

44 Chanabhai P, Holt A, Consumers are ready to accept the transition to online and electronic records if they can be assured of the security measures. MedGenMed. 2007 Jan 11;9(1):8..

45 Alexander Dobrev, Marten Haesner, Tobias Hüsing, Werner B. Korte, Ingo Meyer. "Benchmarking ICT use among General Practitioners in Europe" European Commission 2008. http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_survey_final_report.pdf

46 Hassol A et al. Patient experiences and attitudes about access to a patient electronic health care record and linked web messaging.J Am Med Inform Assoc. 2004 Nov-Dec;11(6):505-13.

47 Hardiker NR, Grant M Barriers and facilitators that affect public engagement with eHealth services. J Stud Health Technol Inform. 2010;160(Pt 1):13-7.

48 JRC IPTS Strategic Intelligence Monitor on Personal Health Systems Phase 2 Country Studies Summary and Evidence Consolidation. Available at http://is.jrc.ec.europa.eu/pages/TFS/SIMPHS2.html

12 documents were analysed to respond this question.

Health systems, health outcomes and the workforce in terms of number and qualifications are different across the EU Member States. Almost half of all Europeans show inadequate or problematic levels of health literacy, according to the results of the European Health Literacy Survey presented in November 2011 at the European Health Literacy Conference.[49] Low health literacy is associated with reduced use of preventive services and management of chronic conditions, and higher mortality. Health literacy is shown as a driver for change for equity and sustainability, influencing the health attitudes of healthy people, people at risk and patients.

The Nairobi Call for Action[50] emphasizes the need to support empowerment by ensuring basic education for all citizens; by building on existing resources and networks to ensure sustainability and enhance community participation; by designing health literacy interventions based on community needs and priorities in their political, social and cultural context and by ensuring that communities are able to access and act on knowledge and overcome any barriers to health. By improving people's access to health information, and their capacity to apply it effectively, health literacy is critical to empowerment. Improving health literacy is an important element of strategies to reduce health inequity.

In general, all papers analysed showed that ICT penetration[51], digital literacy and ICT use is very different in European countries[52,53]. European countries have made substantial progress towards modern eHealth infrastructures and implementations, thereby leading the rest of the world. Following the 2004 eHealth Action Plan the EU Member States committed themselves "to develop a national or regional roadmap for eHealth." Various non-EU countries also followed this vision. In a study funded by European Commission[54] reported that by the end of 2006 most of the EU Member States had published high level official policy documents on their eHealth implementation strategy. In 2010, almost all have detailed documents outlining concrete eHealth goals, implementation measures, and sometimes also their past achievements. In line with the objectives of the eHealth Action Plan 2004, "health authorities' leadership" is visible across the EU. Table 2 identifies key fields of national level activities and the sometimes considerable increase recorded between 2006 and 2010:

Table 1: Key fields of national level eHealth activities in the EU27 countries, 2006 and 2010

49 http://inthealth.eu/research/health-literacy-hls-eu/

50 (World Health Organization) 2009. The Nairobi Call for Action. Final draft. World Conference on Health Promotion.

51 Atlas eHealth country profiles: based on the findings of the second global survey on eHealth. (Global Observatory for eHealth Series, 1). WHO 2011. http://www.who.int/goe

52 Ingo Meyer, Tobias Hüsing, Maike Didero, Werner B. Korte. eHealth Benchmarking (Phase II). European Commission 2009. http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/ehealth_ii_bench_final_report.pdf

53 Deloitte & Ipsos Belgium. "eHealth Benchmarking III" SMART 2009/0022. European Commission 2011. http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/ehealth_benchmarking_3_final_report.pdf

54 Karl A. Stroetmann, Jörg Artmann, Veli N. Stroetmann. "European Countries on their Journey towards National eHealth Infrastructures". European Commission 2011. ISBN: 978-92-79-19766-6 http://ec.europa.eu/information_society/activities/health/docs/studies/eh_strategies/ehealth-strategies_report012011.pdf

Reported eHealth activities	Total 2006 eHealth ERA	Total 2010 eHealth Strategies	Delta
Legal activities	14	22	8
Evaluation	5	21	16
EHR Patient Summary	27	27	0
ePrescription	16	22	6
Telehealth	23	27	4
Patient ID	24	26	2
Professional ID	13	22	9
Citizen card	22	25	3
Professional card	7	18	9
Standards (technical/semantic)	19	27	8

Source: eHealth Strategies study, 2010

Another indication of the strong political commitment at the national policy level is the growing establishment of permanent administrative support structures. Also, the current participation in the *epSOS* project (Smart Open Services for European Patients) undertaken by 23 countries shows the political commitment and interest in the issues.

However, other studies show that telemedicine services such as telehealth, telecare (the home monitoring of patients) or health information networks linking hospitals, laboratories, pharmacies, primary care and social centres often remain small local telehealth or telemedicine experiments, or there are only plans to undertake pilots. Another study[55] demonstrates telemonitoring of outpatients remaining at low levels: only 8% of European acute hospitals do it. Nevertheless, videoconferencing facilities are relatively common. They are available in nearly 40% of the European hospitals surveyed. The most general use of videoconferencing (64%) is for consultation between internal medical staff and external healthcare providers.

Since 2004, rapid development has taken place in the eHealth area in Europe where GPs[56] use a basic ICT infrastructure consisting of computers (87%) and Internet connections (from 61 to 81%). However, in some countries, the share of practices using a computer is as low as 65% (Malta, Romania) or 57% (Latvia). There are considerable differences between the countries, with broadband penetration ranging from 93% in Finland to 5% in Romania.

55 Deloitte & Ipsos Belgium. "eHealth Benchmarking III" SMART 2009/0022. European Commission 2011. http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/ehealth_benchmarking_3_final_report.pdf

56 Alexander Dobrev, Marten Haesner, Tobias Hüsing, Werner B. Korte, Ingo Meyer. "Benchmarking ICT use among General Practitioners in Europe" European Commission 2008. http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_survey_final_report.pdf

The electronic storage of administrative and medical patient data, the use of a computer during consultation with patients and other uses of ICT in healthcare are becoming more and more everyday practices. At the same time, there is still room for improvement when it comes to electronic networks connecting their IT systems with other health actors, the electronic exchange of patient data and electronic interactions with patients. From the data collected for this study, Denmark, the Netherlands, Finland, Sweden and the UK emerge as the European frontrunners in eHealth use by GPs. On the other side there is a group of countries where the use of eHealth at large or the use of advanced applications still leaves considerable room for improvement. This group consists of Greece, Latvia, Lithuania, Poland and Romania. In between lies the large group of average performers, consisting of the remaining 15 Member States. A gap remains between readiness for use and actual use of eHealth. In 2007, further to connections to other health actors, the Internet and other, dedicated networks can also be used for electronic transfer of patient data. Use rates are again moderate to low and show considerable variations.

What is the evidence on the effectiveness and efficiency of eHealth and what research areas still need to build large scale evidence to support wide deployment of telemedicine by 2020?

50 papers on the effectiveness and efficiency of telemedicine services have been analysed. The first results of this systematic review show that the number of trials and projects on telemedicine has dramatically increased in recent years. There is a great variability of trials, technologies, interventions, methodologies, outcomes and indicators which made the assessment difficult. In general, most of the papers confirmed the potential benefits by showing data on effectiveness. However, cost-benefit analysis is often lacking. Great effort should be made in supporting strong evaluation, especially economic evaluation, to ensure the success and the sustainability of the heath system.

Providing decision makers with direct financial figures, statistical data etc., is not enough, since the ultimate strategic objective is to improve the efficiency and quality of clinical care through health ICTs. Methodological difficulties are further exacerbated by data limitations, definition problems and the lack of appropriate sets of indicators on adoption, use and outcome of ICTs which can be compared over time, within and across countries and comparing low cost technologies with expensive ones. Key elements should be investigated, for example, in the field of chronic heart failure, more large-scale trials are required to identify six key elements relating to telephone support and telemonitoring: the best healthcare practices including the optimal frequency of follow up; the patients who benefit; the levels of staffing required; patients' views on the user friendliness of technologies; evidence on efficiency and organizational models[57]. At this point, the recent publication of the Whole System Demonstrator[58] shows very good outcomes. These data could play a key role in the future HTA and decision making process.[59]

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57 Garcia Lizana F. Telemonitoring for chronic heart failure: not ready for prime time. Cochrane Database Syst Rev. 2010 Aug 9;8:ED000009

58 Steventon A et al. Effect of telehealth on use of secondary care and mortality: findings from the Whole System Demonstrator cluster randomised trial. BMJ. 2012 Jun 21;344:e3874. doi: 10.1136/bmj.e3874

59 Ongoing large scale pilot 'RenewingHealth', is pooling together the expertise of European experts and the know-how of local and regional healthcare providers who deliver telehealth services. This project is one of the largest multicentric clinical trial-type exercise across Europe in the field of telemonitoring and telecare services that will fundamentally enhance the body of evidence on the effectiveness of such services. It involves nine countries, and is expected to cover eventually about 8,000 patients.

Findings illustrate the potential benefits that can result from ICT implementation according to four broad, inter-related categories of objectives[61]: increasing quality of care and efficiency; reducing operating costs of clinical services; reducing administrative costs; and enabling entirely new modes of care.

The socio-economic gains are analysed in the study EHR IMPACT (01-2008/02-2009)[60] to support ongoing initiatives and implementation work by the European Commission, Member State governments, private investors, and other actors. The study aims to improve awareness of the benefits and provide new empirical evidence on the socio-economic impact and lessons learnt from successfully implemented systems.

The study shows that the average cumulative socio-economic returns (SER), but not financial return, is 78% over the evaluation timescales of between 9 and 13 years. This confirms that investments in interoperable EHR and ePrescribing systems, if pursued with the necessary rigour, are worthwhile. Once the value of benefits begins to cover costs, the net benefit expands and becomes substantial. Annual net benefit in 2010 reaches between €1.2 million for the smaller-scale sites and over €170 million for Diraya, which serves more than 8 million people. The annual SER increases considerably towards the end of the time scale. The positive SER justifies the wider deployment of interoperable EHR and ePrescribing systems.

The EHR IMPACT study shows interoperability is a prime driver of benefits. It makes life easier for different users and provides gains that rely on access to information regardless of place and time, and from re-using information for multiple purposes. Without meaningful sharing and exchange of information, the gains would be marginal and not justify the cost of investments.

Most of studies responded to three types of interventions: chronic conditions management (27 papers), metal/psychiatric health (12 papers), and health promotion and prevention (8 papers). Eleven documents focused on different interventions or aspects like teledermatology, tele-intensive care, telestroke, etc .

(1) eHealth for improving chronic disease management: these interventions included tele-homecare, telemonitoring in general or for specific diseases like chronic health failure, respiratory diseases, diabetes etc.

Most of the papers showed some benefit, mostly associated to reduction in hospital readmission. However, the data are heterogeneous. Successful adoption and use generally depended on the simultaneous implementation of new service delivery models, integrated models and organisational partnerships[61].

In an extrapolation exercise[62], JRC-IPTS modelled the care institutions' eHealth adoption and expenditure of eHealth by care institutions focusing ion three main chronic conditions

60 Economic Impact of Interoperable Electronic Health Records and ePrescription in Europe (01-2008/02-2009): http://ec.europa.eu/information_society/activities/health/docs/publications/201002ehrimpact_study-final.pdf

61 Garcia Lizana F, Yanes Lopez V. Information and communications technologies in CHF management programmes. Organizational challenges and evidence status. Agencia de Evaluacion de Tecnologias Sanitarias (AETS)Madrid 2009 http://www.isciii.es/htdocs/publicaciones/documentos/56_Tecnol_Inform_Comunic_en_ICC.pdf

62 JRC IPTS Strategic Intelligence Monitor on Personal Health Systems Phase 2 Impact Assessment Report. http://is.jrc.ec.europa.eu/pages/TFS/SIMPHS2.html

(Chronic Heart Failure, COPD and Diabetes) and Telecare. Moreover, the Commonhealth project[63] has published outcomes on cost-effectiveness in several locations and guidelines for integrated eCare services provision based on the evidence they collected.

The Internet can be part of an effective method to increase empowerment of patients who are e.g. suffering from diabetes, depression, infertility or arthritis. Because of the low quality of evidence we found, the results should be interpreted with caution. The clinical relevance of the findings can be questioned because the significant effects we found were, in general, small[64]. However, the outcome empowerment usually refers to achieving self-efficacy, autonomy and control. Although many researchers underline that these tools are closely related to the concept of empowerment, it is still unclear how empowerment is defined, how it should be measured and what is the level of its impact on health outcomes. These gaps indicate the need for more unambiguous research outcomes that lead to better insight into the conditions under which Web-based interventions are effective and how their effectiveness could be maximized.

Krishna et al. [65] conducted a review of 25 papers; and concluded that standard care with reminders, disease monitoring and management, and education through cell phone voice and short message can help improve health outcome and care processes. However, due to the possibility of bias and errors in the review process and the unknown quality of studies including these conclusions may not be reliable.

(2) eHealth for mental health: Most of the studies in this area reported the same benefits as face to face consultation. Several authors supported the use of tele-psychiatry when traditional care is not possible (for instance waiting lists, shortage of professionals in rural areas, etc)[66,67]. However, more research is needed to identify those patients who benefit and to conduct analysis of cost-effectiveness.

Behavioural therapy through the Internet, computer, and telephone applications, even in substance abuse and addiction (alcohol and smoking addictions) are at least as effective as conventional services[68], especially when personalised and interactive settings are utilised.

(3) eHealth impact on health promotion and primary prevention: these interventions included health promotion on healthy behaviour (physical and dietary behaviour, smoking, obesity, alcohol consumption). These findings demonstrate that online interventions have the capacity to influence voluntary behaviours which are routinely targeted by social marketing campaigns. Given the high reach and low cost of online technologies, it may a good tool for

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63 CommonWell is a project co-funded by the EC's ICT Policy Support Programme at four sites in Europe: UK, DE, NL and ES. http://commonwell.eu/norm/commonwell-home/.

64 David Samoocha,David J Bruinvels, Nieke A Elbers,et al. Effectiveness of Web-based Interventions on Patient Empowerment: A Systematic Review and Meta-analysis. J Med Internet Res. 2010 Apr-Jun; 12(2): e23.

65 Krishna S, Boren SA, Balas EA. Healthcare via cell phones: a systematic review. Telemedicine and e-Health 2009; 15(3): 231-240

66 Garcia-Lizana F, Munoz-Mayorga I. Telemedicine for depression: a systematic review. Perspectives in Psychiatric Care, 2010; 46(2):119-126

67 Sloan DM, Gallagher MW, Feinstein BA, Lee DJ, Pruneau GM. Efficacy of telehealth treatments for posttraumatic stress-related symptoms: a meta-analysis. Cognitive Behaviour Therapy 2011; 40(2): 111-125

68 Ohinmaa A, Chatterley P, Nguyen T, Jacobs P. Telehealth in substance abuse and addiction: review of the literature on smoking, alcohol, drug abuse and gambling. HTA report 2010. Institute of Health Economics (IHE). Edmonton http://www.ihe.ca/documents/Telehealth%20in%20Addiction-Final%202%20Arto.pdf

increased public health campaigns that blend interpersonal online systems with mass-media outreach. Such a combination of approaches could help individuals achieve personal goals that, at an individual level, help citizens improve the quality of their lives and at a state level, contribute to healthier societies.

Also, Cugelman B et al[69] found that online interventions have the capacity to influence voluntary behaviours. On the other hand, Car et al [70] showed that due to the small number of studies and their variable methodological quality, the evidence is too weak to draw any conclusions about implications for the design and delivery of interventions for online health literacy. There is a need for well-designed randomised control trials to investigate the effects of such interventions. These should involve different participants (in terms of health status, age, socio-economic group and gender) to analyse the extent to which online health literacy reduces a barrier to using the internet for health information. Trials should be conducted in different settings and should examine interventions to enhance citizens' online health literacy (search, appraisal and use of online health information) like IT training courses, measuring outcomes up to at least one year after the intervention to estimate the sustainability of the intervention effects.

7. VISION AND OBJECTIVES OF THE EHEALTH ACTION PLAN 2012 - 2020

The proposed eHealth Action Plan will run from 2012 until 2020, mirroring the timeline of Europe 2020, the Digital Agenda for Europe and Innovation Union.

The vision of this Action Plan is to utilise and develop eHealth to address several of the most pressing challenges of the first half of the 21st century:

– to improve chronic disease and multimorbidity (multiple concurrent disease) management and to strengthen effective prevention and health promotion practices;

– to increase sustainability and efficiency of health systems by unlocking innovation, enhance patient/citizen-centric care and citizen empowerment; and encourage organisational changes;

– to foster cross-border healthcare, health security, solidarity and universality;

– to improve legal and market conditions for developing eHealth products and services.

7.1. General objectives

The overall policy goal of this Action Plan is to address the challenges outlined above, breaking down persistent barriers and realising the vision of the Europe 2020 Strategy in the area of eHealth.

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69 Cugelman B, Thelwall M, Dawes P Online interventions for social marketing health behavior change campaigns: a meta-analysis of psychological architectures and adherence factors. J Med Internet Res. 2011 Feb 14;13(1):e17.

70 Car J, Lang B, Colledge A, Ung C, Majeed A. Interventions for enhancing consumers' online health literacy. Cochrane Database Syst Rev. 2011 Jun 15;(6):CD007092

7.2. Specific objectives

(5) Improve the quality of life of European citizens

(6) Provide equal access to high quality and sustainable health care systems to all European citizens

(7) Enhance the competitiveness of EU industry through business and expansion of new markets.

7.3. Operational objectives

The Action Plan addresses following operational objectives:

– achieving wider interoperability of eHealth services;

– supporting research, development and innovation in eHealth and wellbeing to address the availability of user-friendly tools and services;

– facilitating uptake and ensuring wider deployment;

– promoting international cooperation.

The Action Plan emphasises cross-border activities but it should be noted that work done at the EU level has a strong effect at a national level and vice versa. Therefore, the Action Plan encourages national and regional authorities, healthcare and social care professionals, industry, patients, service providers, researchers and the EU Institutions to work together towards achieving the objectives listed above.

It should be noted that all operational objectives are closely linked and mutually reinforcing.

8. ADDED VALUE OF AND JUSTIFICATION FOR ACTING AT THE EU LEVEL

Responsibility to define the way to organise and deliver health services and medical care lies within the Member States. In several other areas supporting action from the Commission would be possible, notably under Articles 168, 173, 179 or 114 TFUE.

Taking action at EU level is particularly important given the Commission's role of coordinating Member States' actions and encouraging cooperation between them. Moreover, issues related to cross-border aspects of health (for example, legal uncertainty in particular in the area of recognition of qualifications and liability), identification of common barriers, coordination on common standards and aspects related to the internal market of eHealth applications, as well as the provision of evidence and methodology to assess the effectiveness of eHealth applications, are best addressed at EU level.

Despite their primary competence in the field, Member States require and value the strategic and technical guidance of the Commission in this area[71]. The EPSCO Council has explicitly requested the Commission to provide such guidance by updating the existing eHealth Action

[71] The majority of Member States agree that eHealth would provide a useful tool to meet the challenges faced by European healthcare systems.

Plan. In the Council Conclusions of 1st December 2009 on safe and efficient healthcare through eHealth[72], Member States demonstrated their intention *"to bring forward eHealth deployment and actual use of Interoperable eHealth services within and between national healthcare systems*".

Member States also called upon the Commission to reflect on the progress made so far, to ensure more coherence between health policy developments and eHealth deployment and identify and address in a coordinated manner barriers hampering the deployment of eHealth services which are preventing patients, healthcare systems and society as a whole from fully benefitting from ICT. This shows that Member States welcome the contribution and the added value the Commission brings in supporting the common goals of ensuring high quality, efficient healthcare systems also through the use of ICT solutions. In consistency and complementarity of EU level actions, Member States are encouraged to develop national eHealth Strategies according to international recommendations[73]. These national strategies should integrate the European Innovation Partnership on Active and Healthy Ageing objectives and targets

This action plan responds to the call for support made by Member States in full respect of the principle of subsidiarity. The Action Plan also reinforces the common principles for healthcare in the European Union: universality, access to good quality care, equity and solidarity[74].

The actions focus on European added value by means of pan-European policy actions, transformative research and innovation, and interoperability and deployment in order to facilitate a common eHealth and Well Being innovation space, in which citizens' rights are protected, their mobility across the European Union is facilitated and equity and social cohesion for all is promoted.

The European Commission can provide the platform not only for sharing best practices, experts and lessons learned from number of pilots supported by national and EU programmes, but also can provide guidance on technical and legal framework developments to ensure cross border interoperability and legal certainty. The Commission's role in the area of building trust and improved user acceptance would also be important. A European-wide policy initiative would as well support convergence for common solutions, avoid further market fragmentation and prevent Member States adopting different individual, organisational and technical directions and missing the opportunity to build a common basis for interoperable eHealth applications.

In this context, the policy approach in the Action Plan primarily focuses on cooperation through involvement in pilot projects, the new eHealth Network of Member States[75], the fruitful exchange between health ministries of the Member States and stakeholders, the sharing of best practice, the use of the open method of coordination and the realisation of the Internal Market.

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72 http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/111613.pdf

73 National eHealth strategy toolkit. World Health Organization and International Telecommunication Union 2012. http://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf

74 Council Conclusions on Common values and principles in European Union Health Systems.

75 The Network was established under Article 14 of .Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF, OJ L 88, 4.4.2011,

9. NEXT STEPS FOLLOWING THE COMMUNICATION

As set out in the Action Plan, a number of actions will be implemented at the EU level in 2012 - 2020.

9.1. Review by the Commission of progress made

The Commission will closely monitor the implementation of this Action Plan and report on progress made and results achieved.

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ANNEX: Governance chart for interoperability